REMARKS

Claims 1-29 are pending in the present application. In the Office Action, all claims were rejected. No claims have been amended in this response.

As an initial matter, Applicants thank Examiner Schillinger for helpful and courteous telephone interview conducted on April 16, 2010 with the undersigned attorney of record. During the interview, the arguments presented herein were discussed. The Examiner tentatively agreed that the arguments were persuasive in overcoming the present rejections, but the Examiner also indicated that further review of the Iyer reference was necessary before a final decision could be made.

Claim Rejections – 35 U.S.C. § 102

In the Office Action, claims 1, 2, 5, 7-10, 14, 17, and 28 were rejected under 35 U.S.C. § 102(e) as being anticipated by Iyer et al. (U.S. Patent No. 6,726,923), hereinafter Iyer. Such rejections are traversed for at least the following reasons.

Independent claim 1 currently recites:

> 1. A method of treating a stiffened blood vessel, said method comprising at least substantially encasing a stiffened portion of said blood vessel with **an elastic membrane** formed of biocompatible material, such that said membrane engages said stiffened portion of said blood vessel to thereby **reduce the external diameter** of said stiffened-portion of said blood vessel, **passively carry** at least a portion of blood pressure loads acting on said blood vessel throughout systole and diastole and **reduce the effective stiffness** of said stiffened portion of said blood vessel, said elastic membrane **having a stiffness less than the stiffness of said stiffened portion** of said blood vessel.

Iyer fails to teach or suggest each and every element of the claimed invention. Iyer discloses a method of treating a blood vessel by delivering anti-proliferative drugs or agents to the vessel by way of a prosthetic device in the form of drug-eluting matrix material carrying such drugs/agents and which is applied to the vessels so as to alter the physiological condition of the vessel through

action of the eluted drugs/agents. Applicants respectfully submit that Iyer is irrelevant to the present patent application which is directed to the use of an elastic membrane applied to a stiffened vessel so as to decrease the stiffness of the vessel and, as a result, especially in the case where the membrane is applied to a stiffened aorta, reduce pulse pressure and, accordingly, cardiac load using a simple, passive device. See, for example, page 8, line 35 through page 9, line 16 of the present application.

Firstly, Iyer fails to teach or suggest the use of an elastic membrane. In this rejection the Office Action refers to Iyer's support structure of the prosthetic device as being formed of PTFE (col. 10, line 65 – col. 11, line 56). PTFE, however, is not an elastic material, but instead has plastic mechanical properties. During the interview, the Examiner indicated that the collagen used in Iyer's device could be construed as being an elastic membrane. Applicants maintain that collagen can take many forms, ranging from a soft liquid-like state to a more rigid state after cross-linking, and since Iyer fails to teach or suggest the material properties of the collagen, the cited reference fails to show the identical invention in as complete detail as recited by the claimed invention, hence Iyer fails to teach an elastic membrane, as recited by claim 1.

Iyer also fails to teach or suggest reduction of the external diameter of the stiffened portion of a blood vessel. Each of Figs. 5-13 of Iyer make it quite clear that there is no vessel diameter reduction with application of Iyer's device. Further, given that the device has no structural function, but is merely designed to deliver the drug to the vessel wall, there would be no incentive for a person of ordinary skill to contemplate reducing the diameter of the vessel. Moreover, Iyer's device is used to deliver a drug to a vessel in order to reduce stenosis of the vessel. Thus, one of skill in the art would not place Iyer's device around a vessel and reduce vessel diameter because the reduction in diameter would effectively increase the stenosis, contrary to Iyer's teachings.

Iyer still further fails to teach or suggest a membrane passively carrying at least a portion of blood pressure loads acting on the blood vessel throughout systole and diastole. Contrary to the Examiner's assertions, the passage spanning column 11, lines 21-56 of Iyer does not show that the (non-elastic) PTFE physical structure will act to passively carry at least a portion of blood pressure loads (throughout systole and diastole) that pass through the encased blood vessel. The external PTFE skeleton described acts to support the inner drug eluting

membrane or matrix material (col. 11, lines 30 and 31). Even though reference is made at column 11, lines 38 to 41 of the external PTFE skeleton functioning as an additional reinforcement layer, which may well carry at least a portion of blood pressure load acting during radial expansion of the vessel during systole, there is nothing to suggest that any loads would be carried during diastole. Given that Iyer's device does not reduce the diameter of the vessel, one can only conclude that the prosthetic device does not carry any loads during diastole.

Iyer further fails to teach or suggest reduction of the effective stiffness of the stiffened portion of a blood vessel. Particularly for the embodiments that utilize a PTFE external support skeleton structure or layer (or Dacron polyester as described at column 11, lines 55 and 56), it is expected that the prosthetic device would in fact increase the effective stiffness of the vessel. Furthermore, Iyer's device is also used to provide reinforcement and support to a weakened scar (col. 11, lines 38-41). In order to provide adequate support, Iyer's device would actually have to be stiffer than the vessel. If Iyer's device reduced stiffness of the vessel as suggested by the Office Action, the device would be incapable of providing the necessary support to the weakened scar region, and therefore Iyer's device does not reduce effective stiffness of the blood vessel.

Finally, Iyer fails to teach or suggest the use of an elastic membrane having a stiffness less than the stiffness of the stiffened portion of the blood vessel being treated. Again, it is expected that the stiffness of the prosthetic device of Iyer, particularly the embodiments utilizing either PTFE or Dacron polyester material, would be greater than that of the stiffened portion of the blood vessel.

Because the cited reference fails to teach or suggest each and every element of the claimed invention, anticipation cannot be established under 35 U.S.C. § 102(e). Applicants respectfully request withdrawal of the § 102(e) rejection and allowance of independent claim 1 and the claims depending therefrom.

Moreover, specifically referring to claim 7, Iyer fails to teach or suggest a stiffened portion of blood vessel being in a stiffened and dilatated state prior to treatment. Column 6, lines 56 to 67 of Iyer, to which the Examiner has referred, describes inflammation as a response to the treatment described in Iyer, rather than a pre-condition prior to treatment.

Claim 28 is also clearly patentable over Iyer for similar reasons as set out above in the discussion relating to claim 1. Further, Iyer fails to teach or suggest that the synthetic portion of the blood vessel being treated has a greater stiffness than the stiffness of the native tissue portion. Reference made by the Examiner to column 5, lines 22 to 54 of Iyer does not support any conclusion that the synthetic portion of the blood vessel has a stiffness greater than the native tissue portion.

Because Iyer fails to teach or suggest each and every element of independent claim 28, anticipation cannot be established under 35 U.S.C. § 102(e). Applicants respectfully request withdrawal of the § 102(e) rejection and allowance of claim 28, and the claims depending therefrom.

Claim Rejections – 35 U.S.C.

Iyer in view of Khanghani

Claims 3-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Khanghani et al. (U.S. Patent No. 6,984,201), hereinafter Khanghani. Such rejections are traversed for at least the following reasons.

Claims 3-4 depend indirectly from independent claim 1 which has been distinguished from Iyer as discussed above. Khanghani fails to provide the elements missing from Iyer.

Khanghani discloses an active blood circulation assistance device for location around a blood conduit. The device has an inflatable bladder that is moveable between a contracted form and an expanded form for compressing the blood conduit to provide counterpulsation (Abstract). When the bladder moves from the contracted form to the expanded form at diastole, the blood conduit is compressed and blood in the conduit is displaced, thereby reducing cardiac loading (col. 9, lines 20-29). Khanghani fails to teach or suggest a method of treating a stiffened blood vessel. Moreover, the cited reference also fails to teach or suggest encasing a stiffened portion of the blood vessel. Additionally, Khanghani's device actively inflates and deflates, therefore Khanghani also fails to teach or suggest passively carrying at least a portion of the blood pressure loads, as recited by claim 1. Furthermore, because Khanghani's

inflatable bladder displaces blood in the vessel during diastole, the bladder must be stiffer than the blood vessel to overcome the diastolic pressure therein, and hence Khanghani also fails to teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel, as recited by amended claim 1.

Additionally, one of skill in the art would not combine Khanghani with Iyer. Iyer's device relies on drug delivery to obtain a therapeutic result, whereas Khanghani's device utilizes a pumping device. Combining the two references would require redesign and reconstruction of Iyer's device and would change the basic principle under which Iyer's device operates, therefore the teachings of Iyer and Khanghani are not sufficient to establish *prima facie* obviousness. M.P.E.P. § 2143.01. The combination of Iyer and Khanghani is therefore improper and constitutes impermissible hindsight reconstruction. The claimed invention as a whole, not just its individual elements must be considered and it is inappropriate to use hindsight when guided by the applicant(s)'s disclosure

Therefore, because the cited references, alone or in combination fail to teach or suggest each and every element of the claimed invention, and because one of skill in the art would not combine the cited references, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 3-4.

Iyer in view of Chuter

Claims 6 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Chuter (U.S. Patent No. 5,387,235), hereinafter Chuter. Such rejections are traversed for at least the following reasons.

Claim 6 depends from independent claim 1 which has been distinguished from Iyer as discuss above. Chuter fails to provide the elements missing from Iyer.

Chuter discloses a prosthesis for treating an aneurysm (Abstract), not a method for treating a stiffened blood vessel. Chuter's prosthesis is disposed internally in a vessel (Fig. 15) therefore Chuter's device does not encase a stiffened portion of the blood vessel, nor does his device reduce external diameter of the stiffened portion of the blood vessel and reduce the

effective stiffness of the stiffened portion of the blood vessel, as recited in independent claims 1 and 28.

Moreover, one of skill in the art would not combine Iyer and Chuter. Iyer's device is used for delivery of a drug externally to the vessel, while Chuter's device is implanted internally in a vessel. Implanting a device clearly involves a different principle of operation than Iyer's external device, therefore the combination is insufficient to support a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Claim 29 depends from independent claim 28 which has been distinguished from Iyer for at least the same reasons as discussed above with respect to claim 1. And similarly, Chuter fails to provide the elements missing from claim 29, also, one of skill in the art would not combine Chuter and Iyer as discussed above.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, and because one of skill in the art would not combine the two references, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 6 and 29.

Iyer in view of Barefoot

Claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Barefoot et al. (U.S. Patent No. 3,726,279), hereinafter Barefoot. Such rejections are traversed for at least the following reasons.

Claims 11 and 12 depend indirectly from independent claim 1 which has been distinguished from Iyer as discussed above. Barefoot fails to provide the elements missing from Iyer.

Firstly, Barefoot fails to teach or suggest a method of treating a stiffened blood vessel. Barefoot discloses a hemostatic vascular cuff that is used to control hemorrhaging of suture lines in vessels following vascular surgery (Abstract; col. 4, lines 19-21). The only other application of Barefoot's vascular cuff is described in column 4, lines 12-13, as reinforcing the walls of diseased or damaged vessels. Barefoot does not disclose, teach or suggest using his cuff to treat a stiffened blood vessel by encasing a stiffened portion of the blood vessel, as is also

recited by claim 1. Barefoot further fails to teach or suggest a reduction of the effective stiffness of a stiffened portion of a blood vessel, and the use of an elastic membrane having a stiffness less than the stiffness of the stiffened portion of the blood vessel. Barefoot seeks to control hemorrhaging of a sutured vessel by reinforcing the sutured portion of the vessel. The reinforcement reduces expansion of the sutured portion so that the suture lines will not open up and allow bleeding (see Abstract: column 4, lines 1-11 and column 4, lines 19-21). Accordingly, Barefoot's vascular cuff would seem to have the result of increasing the effective stiffness of the vessel, contrary to what is required of claim 1. It would also follow that the stiffness of the material from which the cuff is formed, which is described as including a semi-rigid core formed from a resilient material such as nylon or polypropylene (see column 1, lines 32-35 and column 3, lines 4-6) would have a stiffness greater than that of the encased portion of the sutured vessel.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants therefore respectfully request withdrawal of the § 103(a) rejection, and allowance of claims 11 and 12.

Iyer in view of Spaulding

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Spaulding (U.S. Patent No. 5,304,200), hereinafter Spaulding. Such rejections are traversed for at least the following reasons.

Claim 13 depends from independent claim 1, which has been distinguished from Iyer as discussed above. Spaulding fails to provide the elements missing from Iyer.

Spaulding discloses a stent, and fails to teach or suggest encasing a stiffened portion of a blood vessel with an elastic membrane as recited in claim 1. Moreover, Spaulding's stent is positioned inside a blood vessel and therefore it does not reduce the external diameter of the stiffened blood vessel, nor does it passively carry at least a portion of blood pressure loads. Because the purpose of a stent is to provide scaffolding to a vessel, it cannot reduce effective stiffness of the stiffened portion of the blood vessel, as also recited by the claim.

Because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established

under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 13.

Iyer in view of Jones

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Jones (U.S. Patent No. 4,202,349), hereinafter Jones. Such rejections are traversed for at least the following reasons.

Claim 15 depends indirectly from independent claim 1 which has been distinguished from Iyer as discussed above. Jones fails to provide the elements missing from Iyer.

Jones discloses markers that are attached to a blood vessel in order to allow verification of pulsatile blood flow under fluoroscopy by observing movement of the markers (Abstract). Therefore, Jones fails to teach or suggest a method of treating a stiffened blood vessel or encasing a stiffened portion of the blood vessel with an elastic membrane. Moreover, Jones also fails to teach or suggest reducing external diameter of the stiffened-portion of the blood vessel, reducing effective stiffness of the blood vessel or carrying at least a portion of the blood pressure loads, all recited in the claim.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claim 15.

Iyer in view of Dusbabek

Claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Dusbabek et al. (U.S. Patent Publication No. 2001/0007082), hereinafter Dusbabek. Such rejections are overcome for at least the following reasons.

Claim 16 depends indirectly from independent claim 1 which has been distinguished from Iyer as discussed above. Dusbabek fails to provide the elements missing from Iyer.

Dusbabek's system is placed inside a blood vessel and thus Dusbabek's system does not encase a stiffened portion of the blood vessel, nor does it reduce the external diameter of the stiffened blood vessel and reduce the effective stiffness of the stiffened portion of the blood vessel, as recited in claim 1.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claim 16.

Iyer

Applicants note that the Office Action states that claims 18-24 are rejected under 35 U.S.C. § 103(a) as being "anticipated" by Iyer et al. (Office Action, page 6). Applicants assume that use of the term "anticipated" was a typographical error, and have responded to the rejection under the assumption that the that the Office Action should have stated "unpatentable." If this is not the case, Applicants would appreciate the opportunity to respond appropriately.

Claims 18-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer. Such rejections are traversed for at least the following reasons.

Claims 18-24 depend either directly or indirectly from independent claim 1 which has been distinguished from Iyer as discussed above. Therefore, for at least the same reasons discussed above, claims 18-24 are also distinguished from Iyer.

Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 18-24.

Iyer in view of Silvestrini

Claims 25-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Silvestrini et a. (U.S. Patent No. 4,834,755), hereinafter Silvestrini. Such rejections are traversed for at least the following reasons.

Claims 25-26 depend directly from independent claim 1 which has been distinguished from Iyer as discussed above. Silvestrini fails to provide the elements missing from Iyer.

Silvestrini's device, when used as a vascular prosthesis, is used to replace a section of a blood vessel. Therefore, Silvestrini fails to teach or suggest encasing a stiffened portion of the blood vessel and reducing the external diameter of the stiffened portion of the blood vessel. Moreover, Silvestrini also fails to teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claims 25-26.

Iyer in view of Wellman

Claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Iyer in view of Wellman et al. (U.S. Patent Publication No. 2003/0065303), hereinafter Wellman. Such rejections are traversed for at least the following reasons.

Claim 27 depends directly from independent claim 1 which has been distinguished from Iyer as discussed above. Wellman fails to provide the elements missing from Iyer.

Wellman discloses a method of treating diseased blood vessels, and particularly diseased blood vessels that have a narrowed blood vessel lumen, and thus reduced effective diameter. Such vessels are treated by increasing the effective diameter of the diseased blood vessel and maintaining the increased diameter for a sufficient period of time (see, for example, paragraphs 0003, 0005, 0006 of Wellman). The exemplary embodiments are described in terms of the diseased blood vessel having an atherosclerotic plaque along its wall (see, for example, paragraphs 0008, 0009 and 0033 and atherosclerotic plaque 120 depicted in Figure 1). The existence of atherosclerotic plaque on a blood vessel wall does not, however, result in a stiffened blood vessel as discussed in the last response. Accordingly, a blood vessel exhibiting atherosclerotic plaque along its wall cannot be considered a stiffened blood vessel.

Wellman further fails to teach or suggest reducing the external diameter of a blood vessel. The methods of Wellman all involve disrupting the integrity of at least one layer of the diseased blood vessel, promoting the growth of an aneurysm either by way of chemical

treatment (for example, application of a proteolytic enzyme directly to the blood vessel) or by mechanical treatment (such as by puncturing the blood vessel wall). The methods of treatment of Wellman are all thus directed at increasing the diameter of the diseased blood vessel, through growth of an aneurysm, rather than reducing the diameter of a stiffened portion of a blood vessel, as is the case with the present invention.

Wellman also fails to teach or suggest the use of an elastic membrane formed of biocompatible material. The body 52 of the sponge 50 depicted in Figure 5 of Wellman, is not an elastic membrane but merely a topical drug applicator that is loaded with an active therapeutic agent and placed on the affected vessel, providing for delayed drug delivery to a diseased region of a blood vessel. While the body 52 of the sponge 50 is described at paragraph 0041 of Wellman as providing mechanical support to the diseased region of the blood vessel, this support would only be temporary and relatively inconsequential. The sponge 50 is described (at paragraph 0042) as being formed of a bioabsorbable polymer such that it will be absorbed (and thereby effectively disappear) once it has carried out its primary purpose of delivering a therapeutic agent to the blood vessel over a relatively short period of time. The sponge 50 must also allow for an increase in the diameter of the blood vessel as the aneurysm grows.

Wellman further fails to teach or suggest reduction of the effective stiffness of a stiffened portion of a blood vessel, or use of an elastic membrane having a stiffness less than the stiffness of the stiffened portion of the blood vessel. As noted above, Wellman is not directed whatsoever to a method of treating a stiffened blood vessel by reducing the diameter of the blood vessel, reducing the effective stiffness of the blood vessel as noted above. Wellman, and particularly the embodiment depicted in Figure 5, is directed at utilizing a sponge merely to deliver a therapeutic agent to a diseased portion of a blood vessel over a limited period, and then bioabsorb to allow for the growth of an aneurysm to thereby increase the diameter of the blood vessel. The disclosure of Wellman provides no incentive for a person of ordinary skill in the art to consider use of an elastic membrane and the stiffness properties to reduce the external diameter of a stiffened portion of a blood vessel and reduce the effective stiffness of that stiffened portion of a blood vessel. Wellman in fact teaches directly away from the present invention, promoting a substantial increase in the diameter of a diseased blood vessel through growth of an aneurysm.

Wellman also fails to teach or suggest the use of an elastic membrane to passively carry at least a portion of blood pressure loads acting on the blood vessel throughout systole and diastole. The sponge 50 of Wellman merely acts to carry and deliver a drug to a diseased portion of a blood vessel and generally support the blood vessel. There is no suggestion that the sponge carries blood pressure loads acting throughout systole and diastole, and there would certainly be no incentive for a person of ordinary skill in the art to configure a sponge in such a manner, given its purpose. Further, with the sponge of Wellman being described as being bioabsorbable, it would clearly be unable to carry any loads once it has been absorbed.

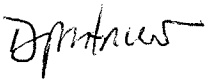
Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claim 27.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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